Informed consent

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CME

ETHICS CME, Part 3 of 3

Target audience: All physicians

Learning objectives:

1. Understand that the informed consent process requires more than simply securing permission for treatment
2. Understand what a physician must do to secure a patient's informed consent
3. Understand that conduct during the consent process can affect different legal claims against a physician

Faculty credentials/disclosure:

Russell G. Thornton, JD, is an attorney specializing in defending medical malpractice suits. Mr. Thornton has no significant financial relationships to disclose.

Before beginning this activity, please read the instructions for CME on p. 201. This page also provides important information on method of physician participation, estimated time to complete the educational activity, medium used for instruction, date of release, and expiration. The quiz, evaluation form, and certification appear on pp. 201–203 as well.

The doctrine of informed consent is based upon the right of every individual to determine what shall be done to his or her body in connection with medical treatment (1). To exercise this right, the patient is entitled to information of a sufficient nature to allow him or her to make an informed decision on whether or not to consent or refuse treatment (2). Because patients are entitled to this information, physicians have a duty to make reasonable disclosures to their patients about the risks associated with proposed treatment (3). In Texas, the physician is required to make reasonable disclosure of the risks of medical treatment and must secure the authority or consent of the patient to legally perform a medical procedure (4). In 1977, the duty to obtain a patient's informed consent was codified in statute (5). This statutory scheme governs informed consent claims.

TEXAS LAW AND INFORMED CONSENT

Under Texas law, "informed consent" describes the physician's duty to disclose to the patient the risks and hazards of medical care that would influence a reasonable person's decision to give or withhold consent to that treatment (5). While a claim based on informed consent focuses on whether or not the health care provider advised the patient of the risks and hazards of a particular treatment or procedure, the significance of the informed consent process in health care liability claims is not limited solely to claims that involve an alleged failure to advise a patient of such risks and hazards. The informed consent process, and the information conveyed therein, can play a significant role in cases that involve surgical claims, claims related to complications from procedures, claims where an election of treatment or alternative modes of treatment for a specific condition are at issue, and claims focusing on the physician's attention to detail in providing care and treatment to patients.

Given that informed consent can be so far-reaching, physicians should treat this facet of care seriously in terms of their efforts and documentation. A failure to do so can result in additional claims or complicate the defense of a case in litigation. The small extra effort needed to perform and document this function adequately will pay off greatly if a physician's care is reviewed to investigate a potential suit. Further, documentation will provide counsel with beneficial information to be used during the litigation process if a claim is filed and pursued.

THE DUTY TO OBTAIN INFORMED CONSENT

The duty to obtain a patient's consent for treatment rests on the patient's treating physician (6). Hospitals, nurses, surgical assistants, and referring physicians do not owe this duty to their patients (7). The treating physician's duty to obtain a patient's informed consent cannot be delegated (8). The duty is not eliminated, lessened, or spread by having the hospital nurse secure the patient's consent before surgery (8).

Under 2 situations, however, Texas courts have left open the possibility that a hospital or nurse might also be exposed to liability for conduct in the informed consent process. The first possibility involves a circumstance in which the hospital or nurse agrees to undertake the treating physician's nondelegable duty (9). This action does not allow the physician to escape liability for failing to obtain the patient's consent (8). This situation only exposes the hospital or nurse to liability that would not otherwise exist.

Second, a nurse's failure to report a discrepancy between the patient's understanding of the surgery to be performed and the surgery listed on the patient's records may create liability (10).

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If expert testimony establishes that the nurse had a duty to notify the physician of such a discrepancy, a negligence claim exists against the nurse (11).

STATUTORY REQUIREMENTS

Article 4590i, Section 6.01 *et seq.* of the *Texas Revised Civil Statutes Annotated* govern claims based on informed consent. This statute has survived a recent constitutional challenge (12). Under this statute, the Texas Medical Disclosure Panel was created to evaluate medical and surgical procedures and determine whether disclosure is required for them. If disclosure is required, the panel determines what disclosure is required (13). Once evaluated by the panel, procedures are placed on one of 2 lists. List A contains all procedures that require disclosure and the specific disclosure required. List B contains all procedures that require no disclosure. Information about the procedures currently on List A and List B can be obtained directly from the panel.

A physician's conduct may be presumed appropriate when he or she discloses risks set forth in connection with medical procedures found on List A or provides no disclosure for medical procedures on List B (5, 14). These presumptions may be rebutted by expert testimony that additional risks and hazards should be disclosed for certain List A procedures or that certain List B medical procedures require disclosure of specific risks and hazards (15).

Procedures not on List A or List B

If the disclosure panel has not evaluated a procedure and published its determinations on disclosure, the physician's duty is to inform the patient of the risks inherent in the procedure or treatment that would influence a reasonable person's decision to consent to the treatment (16). To have a claim, the patient must prove that a reasonable person, not the patient himself, would have refused the treatment or the procedure if fully informed of the inherent risks allegedly not disclosed (17).

In order for a risk to be "inherent," it must exist in connection with and be inseparable from the treatment or procedure (16). Expert testimony is necessary to establish that a risk is "inherent" to the treatment or procedure in question (16, 18). Corrective or remedial measures subsequently performed to treat a risk or hazard of treatment that occurs are not "inherent" risks and need not be disclosed (16, 19). Thus, complaints about nondisclosure of additional or future treatment necessary due to a treatment side effect or complication are not actionable (16).

Disclosure necessary

Appropriate disclosure occurs when the patient consents to the treatment in question and signs an authorization (consent form) that contains disclosure of the procedure's inherent risks, hazards, and side effects (20). A sample form—with blanks for insertion of the condition, treatment, and risks involved—is contained in the List A and List B materials that can be obtained from the disclosure panel. If the patient signs a form that contains the necessary information, proper disclosure is established, unless there is further expert testimony, as discussed above, or pleading and evidence of fraud, mistake, accident, undue influence, or mental incapacity in connection with the execution of the authorization (15, 21). An allegation and statement by the plaintiff that he or she saw nothing on the disclosure form when it was signed is generally insufficient (21). A more detailed factual statement about a signature on a blank form may, however, be sufficient to create an issue of fact on disclosure (22).

OTHER POTENTIAL CLAIMS

While Section 6.01 establishes that the statutory scheme discussed above is the only claim available for a patient who complains of the failure to be advised of the risks and hazards associated with a procedure, the statute does not eliminate other bases of liability and/or claims that may arise from a physician's conduct during the consent process. For example, a claim of common law fraud may be based on misrepresentations about the results of surgery or failure to disclose the full extent of the surgery to be performed (23). Since the doctrine of informed consent applies only to failure to disclose the risks and hazards of treatment, a separate cause of action for common law fraud, outside of the statute, could exist for misrepresentation of matters discussed during the consent process that do not pertain to a risk or hazard of treatment (23, 24). Further, intentional conduct, such as intentional withholding of information during the consent process, may give rise to a cause of action for violation of the Texas Deceptive Trade Practices Act (25).

CIRCUMSTANCES IN WHICH INFORMED CONSENT IS REQUIRED

Numerous circumstances exist in which consent should be provided and documented. The most obvious circumstance is when a surgical procedure is performed on the patient.

The physician has a duty to obtain "informed" consent, not just permission. Review of countless medical records in the context of litigation reveals that many practitioners view the informed consent process as only requiring permission to operate. The focus is simply on securing the patient's signature on a document that says little more than that the physician is authorized to perform the procedure. Often, at best, the form describes vague and broad complications—such as infection, bleeding, or death—that may occur. To adequately discharge his or her duty, the physician must advise the patient of the specific risks of the procedure. The physician is not required, however, to advise a patient that he or she may be more likely to suffer a certain risk or complication because of an underlying condition (26). Disclosure of the general risks that are associated with any surgical procedure is usually inadequate. If alternative surgical procedures or conservative nonsurgical therapy is discussed, the discussion should be quickly documented in the patient's chart.

When any type of prosthetic device is used, informed consent should be obtained with respect to the specific device. A perfect illustration is the silicone gel–filled breast implant litigation. While researchers eventually established that there was no link between silicone gel–filled breast implants and the systemic diseases alleged by claimants, the frequent absence of any device-specific consent references or documentation complicated the defense of many surgeons. Surgeons with detailed, device-specific consent were much easier to extract from litigation, and claims against them were generally dismissed much earlier in the litigation than claims against those who did not provide documentation.

Another significant benefit of detailed consent is that it thwarts product manufacturers' attempts to shift blame to the

treating physicians. While a defense still exists that the product manufacturer did not adequately convey the risks of the product to the physician, the absence of good documentation of the consent process provides the manufacturers with ammunition to argue that the physician simply did not convey any specific risks to the patient, thus making plaintiff's counsel hesitant to dismiss the physicians from the litigation.

Similarly, when a physician institutes a medical regimen for treatment of a problem, particularly when it involves a nonmainstream, somewhat controversial, or new medical regimen, documentation should show that the risks and hazards of the treatment were discussed and accepted by the patient. Physicians should also document that the patient was informed of any limitations that existed, such as the fact that the medical regimen had not yet been widely investigated.

A perfect illustration is the current diet drug litigation. In this litigation, some physicians did a fine job of documenting that the specific and significant risks and hazards of the regimen were discussed and that the patient was informed that this regimen was in the developmental stages. Some physicians had their patients sign the chart where these discussions were documented. This documentation and small extra effort has been of great benefit to defense counsel in defending these claims. Further, as with the breast implant litigation, this documentation has served to rebuff efforts by the medication's manufacturer to shift blame to the physicians and absolve itself of any responsibility.

Unfortunately, a lesson to be learned from the silicone gel–filled breast implant litigation and the diet medication litigation is that health care providers should not assume that a product manufacturer will defend its product when substantial litigation arises. These 2 instances have shown us that the manufacturers pursue, or allow their counsel to pursue, a strategy to shift the entire blame for any complications that result from the product's use to the physicians. This important factor must be kept in mind by physicians using such medical devices and medications. This is a further reason to discuss and document device and medication-specific regimens.

Some medical regimens are essentially surgical in nature and should be treated as surgical procedures for informed consent purposes. Examples are chemotherapy treatment regimens and thyroid ablations. Additionally, when a patient receives a treatment regimen that involves multiple medications, documentation that the specifics of the medical regimen were discussed with the patient and that the patient was informed how and why to use each medication is beneficial. An example is asthma treatment regimens. Patients are commonly provided 3 medications that are each used for specific circumstances: 1 or 2 daily medications prevent flare-ups and 1 medication combats sudden attacks. The medication labels and the literature that explains their use state that the daily medications should not be used in emergency situations. Problems exist when patients use the wrong medication. Given that this mistake can result in significant morbidity or mortality, an argument exists that this mistake is a risk of the particular medication and should be disclosed. Even if that is not the case, documentation specific to the use of the medications will prevent or minimize future disputes over those matters.

Use of conservative therapeutic measures—such as physical therapy, work hardening, chiropractic manipulations, radiation therapy, laser treatment for skin and vein lesions, trigger point and facet block injections for chronic pain, and conservative therapies to treat conditions such as thoracic outlet syndrome—should also have informed consent. All of these procedures have potential risks and complications. The patient should be advised of these matters. Additionally, medical or surgical alternatives may be available. The fact that these alternatives were discussed with the patient and that the patient chose to proceed with the more conservative measures should be documented.

In certain circumstances, the timing of the procedure should be discussed with the patient. Most commonly, these circumstances arise when a patient desires to postpone a surgical or therapeutic intervention because of a vacation or family, work, or insurance concerns. Claims that center on why a procedure was not performed earlier are not infrequent. A small amount of documentation at the time, particularly if the patient could have significant complications from delay of the procedure, can prevent future litigation. If litigation does arise, the documentation can be persuasive evidence for counsel when defending the claim.

THE VALUE OF GOOD DOCUMENTATION

The informed consent process can also be used by counsel as an indirect means of establishing whether a physician or his or her medical practice is detail oriented. In most health care liability claims, the key player is the physician. The physician's conduct and credibility are very important. Evidence that a physician fully involves the patient in selecting treatment options, timing the treatment, and reviewing the risks and hazards associated with that treatment is beneficial. This evidence can be used by counsel to establish a physician's credibility beyond his or her own conduct at deposition or trial. It creates information the jury can review during deliberations. The absence of this detail in a physician's chart can hinder counsel, even if the physician is very charismatic and presents very well at deposition or trial. Sloppy documentation by a physician who does not present well can be troublesome and damaging.

This discussion may lead to queries about what exactly should be documented and where the documentation should stop. These are valid questions and concerns. Health care providers cannot spend all of their time documenting information about patient office visits. Simple steps can be taken, however, to minimize problems and provide counsel with beneficial and useful information.

The most important step is to ensure that the consent form used by the hospital and signed by the patient functions as good documentation and is informative. The risks and hazards should be spelled out on the form signed by the patient. Sometimes under the "Risks and Hazards" section of the consent form broad, vague phrases like "as discussed" or "per previous discussions" are used. These phrases are neither informative nor helpful, particularly if the physician's office documentation about preoperative discussions and concerns is sparse or nonexistent.

Some hospitals and facilities have moved toward attaching List A from the Texas Medical Disclosure Panel to the form and referencing the specific sections of that list that pertain to the

procedure or treatment involved. That is helpful. In those situations, physicians should remember that they are relying upon nursing personnel that they may not know and do not have control over to both discuss and document this procedure. They should not assume that other individuals will adequately carry out that process. Remember, the duty to obtain a patient's informed consent rests on the physician, not on nursing personnel (6). If the nurses do not do it correctly, the physician is responsible.

If nurses are relied on in this manner, the physician should have office documentation or documentation in the hospital chart progress notes showing the specific risks and hazards of the procedure and the discussion of these risks with the patient. Since the physician should personally discuss the risks and hazards of a procedure with the patient, this can be easily documented at the time of that discussion, whether in the hospital or the office. Since many physicians now dictate their office notes and have them transcribed, the addition of this information to a physician's dictation is not very time-consuming or burdensome.

The importance of adequate documentation in medical records cannot be overstated. Documentation of the consent process is particularly important, since this is an obligation that is specifically placed on a physician and is spelled out in a statute. Further, the consent process itself can affect many potential claims that can be brought against a health care provider. It can be utilized in support of or against the health care provider, depending upon the amount of attention that has been devoted to it in the physician's documentation. Thus, it is part of a patient's health care that should not be overlooked or minimized.

1. *Johnson v. Whitehurst,* 652 S.W.2d 441, 444 (Tex. App.—Houston [1st Dist.] 1982, writ ref'd n.r.e.).
2. *Wilson v. Scott,* 412 S.W.2d 299, 301 (Tex. 1967).
3. *Wilson,* 412 S.W.2d at 301.
4. *Wilson,* 412 S.W.2d at 301; *Powers v. Floyd,* 904 S.W.2d 713, 715 (Tex. App.—Waco 1995, no writ); *Johnson,* 652 S.W.2d at 444.
5. *Peterson v. Shields*, 652 S.W.2d 929, 931 (Tex. 1983); Texas Revised Civil Statutes Annotated, art. 4590i, §§ 6.02, 6.05 (Vernon's Supp. 1999).
6. *Nevauex v. Park Place Hospital*, 656 S.W.2d 923, 925 (Tex. App.—Beaumont 1983, writ ref'd n.r.e.).
7. *Boney v. Mother Francis Hospital*, 880 S.W.2d 140 (Tex. App.—Tyler 1994, no writ); *Gibson v. Methodist Hospital*, 822 S.W.2d 95, 100–101 (Tex. App.—Houston [1st Dist.] 1991, writ den'd); *Ritter v. Delany*, 790 S.W.2d 29, 32 (Tex. App.—San Antonio 1990, no writ); *Johnson v. Whitehurst*, 652 S.W.2d 441, 445 (Tex. App.—Houston [1st Dist.] 1983, writ ref'd n.r.e.); *Ross v. Sher*, 483 S.W.2d 297, 301 (Tex. Civ. App.—Houston [14th Dist.] 1972, writ ref'd n.r.e.); *Weiser v. Hampton*, 445 S.W.2d 224, 231 (Tex. Civ. App.—Houston [1st Dist.] 1969, writ ref'd n.r.e.).
8. *Boney*, 880 S.W.2d at 143; *Ritter*, 790 S.W.2d at 32.
9. See *Gibson*, 822 S.W.2d at 100–101; *Ritter*, 790 S.W.2d at 32.
10. See *Urban v. Spohn Hospital*, 869 S.W.2d 450 (Tex. App.—Corpus Christi 1993, writ den'd).
11. *Urban*, 869 S.W.2d at 453.
12. *Penick v. Christensen*, 912 S.W.2d 276 (Tex. App.—Houston [14th Dist.] 1995, no writ).
13. Texas Revised Civil Statutes Annotated, art. 4590i, § 6.04 (a) (Vernon's Supp. 1999).
14. Texas Revised Civil Statutes Annotated, art. 4590i, § 6.07 (Vernon's Supp. 1999).
15. *Penick*, 912 S.W.2d at 287; *Merckling v. Curtis*, 911 S.W.2d 759, 769 (Tex. App.—Houston [1st Dist.] 1995, no writ).
16. *Jones v. Papp*, 782 S.W.2d 236, 240 (Tex. App.—Houston [14th Dist.] 1989, no writ).
17. *McKinley v. Stripling*, 763 S.W.2d 407, 410 (Tex. 1989).
18. *Harfiel v. Owen*, 618 S.W.2d 902, 905 (Tex. Civ. App.—El Paso 1981, writ ref'd n.r.e.).
19. *Jones v. Papp*, 782 S.W.2d 236, 241 (Tex. App.—Houston [14th Dist.] 1989, writ den'd).
20. Texas Revised Civil Statutes Annotated, art. 4590i, § 6.02 (Vernon's Supp. 1999).
21. *Drummond v. Hodges*, 417 S.W.2d 740, 747 (Tex. Civ. App.—Dallas 1967, no writ).
22. See *Johnston v. Vilardi*, 817 S.W.2d 794 (Tex. App.—Houston [1st Dist.] 1991, no writ).
23. *Melissinos v. Phamanivong*, 823 S.W.2d 339, 344–345 (Tex. App.—Texarkana 1991, no writ).
24. See *Julian v. Jackson*, 694 S.W.2d 434, 436 (Tex. App.—Dallas 1985, no writ).
25. See *Chapman v. Wilson*, 826 S.W.2d 214, 219 (Tex. App.—Austin 1992, no writ).
26. *Crundwell v. Becker*, 981 S.W.2d 880, 883 (Tex. App.—Houston [1st Dist.] 1999, writ den'd).